Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D2164764	07/19/2023
Name of Provider or Supplier	**Street Address, City, State**	
Msrc, Llc	102 Patrick St Plaza, Charleston, WV	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An announced, on site, routine recertification survey was conducted at MSRC, LLC on July 19, 2023, by the West Virginia Office of Laboratory Services. The laboratory was assessed for compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies are cited below.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview the laboratory failed to monitor and document the water quality and utilize NIST calibrated thermometer /hydrometers to ensure accurate and reliable test system operation. Findings: 1. No documentation of the water quality for January 2023 thru date of survey could be located. 2. The thermometer/hydrometer used to monitor the environmental conditions of the laboratory analyzers has a NIST calibration that expired 9/27/21. 3. An exit interview with the technical supervisor, 7/19/23 at approximately 2:00 PM, confirmed that no documentation of water quality could be located for 2023 and the environmental conditions were being monitored from a thermometer/hydrometer with an expired NIST calibration.
D5437	CALIBRATION AND CALIBRATION VERIFICATION

	CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on written policies and procedures, record review, and interview the laboratory failed to (2) follow the calibration procedures established in the validation of the Sciex toxicology analyzer in October 2022. Findings: 1. Review of the validation binder for the Sciex identified a calibration policy stating each analyte will have a low calibrator that is 75% of the established cutoff. 2. Review of June 2023 calibration records for 4 of the 36 analytes (buprenorphine, fentanyl, hydrocodone, oxycodone) revealed the following: buprenorphine cutoff for positive result 25, lowest calibration point 80 fentanyl cutoff for a positive result 10, lowest calibration point 80 hydrocodone cutoff for a positive result 50, lowest calibration point 80 oxycodone cutoff for a positive result 50, lowest calibration point 80 3. An exit interview with the technical supervisor, 7/19/23 at approximately 2:00 PM, confirmed that the calibration for the analytes did not meet the established criteria of the validation of the Sciex analyzer.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on written policies and procedures (P&P), record review, and interview the laboratory failed to (c) document quality assessment (QA) activities for 3 of 3 months reviewed in 2023. Findings: 1. "Quality Control Program " P&P states a monthly review of analytic test system to be completed on "Quality Control Monthly Review" form. 2. No documentation for the monthly QA of the analytic systems could be located for April, May, and June 2023. 3. An interview with the technical supervisor, 7/19/23 at approximately 1:00 PM, confirmed the lack of documentation for the QA of the analytic system in April, May, and June 2023.